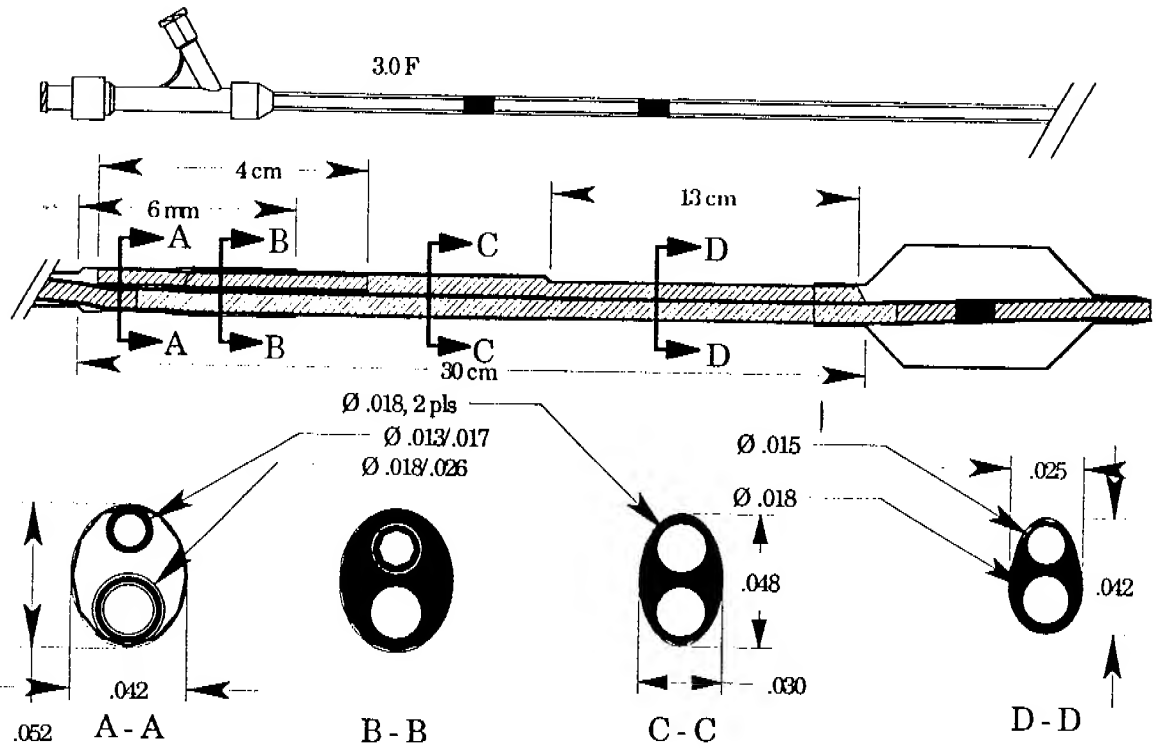
Exhibit 35

Dan Wilt 6/24/94

CONFIDENTIAL

.014 Platform Elliptical OTW

Dan Cox
6-10-94



VR Cherry 6/24/94

Dan Wilt 6/24/94

E. Wilson 6/24/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: D14 Platform OTW Date: 5/27/94

Project Engineer: Dan Cox Wet: ✓ Dry: _____

Clinical Research Coordinator: Colleen McQueen

Control Catheter Used: _____

Guiding Catheter: 7F JL 3.5 PG Guide Wire: Transp

Product design/performance goals: 3.0 F

(1) Coaxial distal PEEK Proximal, Graphite/PE Inner member
Atatrin 6410 Distal outer shaft 2.9F to 2.7F, 3.0 PE600

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	○	○	○
Comments: not too stiff					
2. Tip length:	○	○	○	○	○
Comments: Acceptable, like base					
3. Smoothness of transition:					
A. Distal tip to balloon:	○	○	○	○	○
B. Balloon to shaft:	○	○	○	○	○
C. Shaft transitions:	○	○	○	○	○
Comments: A: Transitionless, very nice B: Pretty good C: A little stiff area pretty well					
4. Flexibility of shaft:					
A. Proximal shaft:	○	○	○	○	○
B. Distal shaft:	○	○	○	○	○
Comments: A: Stiff B: Flexible both nice					

(See Reverse)

VK Chang

E. Wilson 6/24/94

5. **Ease of prep:** Prep method: _____

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

6. **Inflation and deflation times:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Inflation time: _____ Deflation time: _____

Contrast & dilution: _____ Inflation device: _____

Comments: _____

7. **General appearance of dilatation catheter during inflation and deflation (note bowing and folding):**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

8. **Trackability:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Takes tight radius real well

9. **Pushability:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Good 1:1 transmission

10. **Guide back out:** Yes ___ No ___

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: No guide movement lightly seated in 046 lesion

11. **Guide wire movement:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Outside model 4.8/5.0

12. **Dimensions (list size and area):**

_____ _____

_____ _____

_____ _____

13. **Did product meet design goals?** Yes ___ No ___

Overall comments:

_____

_____

_____

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

6/24/94

6/24/94

6/24/94

Eric Wilson 6/24/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 5/27/94

Project Engineer: Dan Cox Wet: ✓ Dry: ____

Clinical Research Coordinator: Colleen McQueen

Control Catheter Used: ____

Guiding Catheter: ____ Guide Wire: ____

(2) Product design/performance goals:
Elliptical distal. Coaxial proximal 3.0F PEEK, graphite/PE inner member
Distal necked from .029/.049 to .024/.045 about 3.0 PE 600

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	○	○	○
Comments:					
2. Tip length:	○	○	○	○	○
Comments: Looks a little longer than ① Looks nice					
3. Smoothness of transition:					
A. Distal tip to balloon:	○	○	○	○	○
B. Balloon to shaft:	○	○	○	○	○
C. Shaft transitions:	○	○	○	X	○
Comments: A: More step up to fold B: Rough- had a bump at this junction About like ① A little more noticeable because distal is softer. Kinkable at hub 4:2 stiffness change is 4:3 for ①					
4. Flexibility of shaft:					
A. Proximal shaft:	○	○	X	○	○
B. Distal shaft:	○	○	○	X	○
Comments: B: Wimpy on distal necked section Unorked alright but wimpier than ①					

VRChenny 6/24/94

(See Reverse)

Eric Wilson 6/24/94

5. **Ease of prep:** Prep method: _____

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

6. **Inflation and deflation times:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Inflation time: _____ Deflation time: _____

Contrast & dilution: _____ Inflation device: _____

Comments: _____

7. **General appearance of dilatation catheter during inflation and deflation (nose bowing and folding):**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

8. **Trackability:**

Significantly Better ○ | Somewhat Better ○ | Same As X | Somewhat Worse ○ | Significantly Worse ○

Comments: Can feel proximal transition but still tracks well

9. **Pushability:**

Significantly Better ○ | Somewhat Better ○ | Same As X | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

10. **Guide back out:** Yes ___ No ___

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: No backout until proximal seal hit lesion

11. **Guide wire movement:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse X | Significantly Worse ○

Comments: Sticky

12. **Dimensions (list size and area):**

_____ _____

_____ _____

_____ _____

13. **Did product meet design goals?** Yes ___ No ___

Overall comments:

Slight performance Edge for coaxial in wire movement

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

E. Wilson 6/24/94

E. Wilson 6/24/94

VR Chaney 6/24/94

Eric Wilson 6/24/94

Date: 6/21/94

Title: Coax w/PEEK - Elliptical Distal (with a 100% HDPE a 75/25 HDPE/LLDPE and a 83/13/4 HDPE/LLDPE/GRAPHITE distal elliptical)

Objective: To evaluate these catheters to determine if the stiffer materials (100%HDPE and 83%/13% 4% HDPE/LLDPE/GRAPHITE) perform better than the softer 75/25 material. I.e., prevent prolaspe

Procedure: **Note:** Ref drawing for dimensions

Tooling: .011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.
.025, .031, .039. 043 and .048 Teflon capture tubing.
Razor blades, Hot box, and Induction heater

Materials:

Description	Part Number	Comments
Elliptical dual lumen	N/A R&D	75/25 Alathon/LDPE
Elliptical dual lumen	Ext. # 10-465-T	100% HDPE
Elliptical dual lumen	Ext. # 12-194-B	83% HDPE w/13% LLDPE + 4% Graphite
IM	Ext. # 13-88-A	Graphite
Intermediate shaft	Ext. # 12-083	Alathon 6210
IM	Ext. # V-466-1	Graphite
Stiff Shaft	Vendor# 02-149	PEEK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	----------
Distal tip Material	Ext. # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	----------
Gold Bands	RM500340	----------
Loctite	RM60563	414
Loctite	RM60124	420
Loctite	RM60562	350

Assembly Instructions: (Distal Elliptical)

- Cut approximately 40 cm of the elliptical shaped tubing.
- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to .026 x .045 +/- .001.
- **Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm** Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

Distal Tip:

- Cut the graphite to approximately 20 cm.
- Neck the graphite to .021 OD using an autonecker.
- **Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm**
- Slide the gold band over the necked portion.

RChung 6/24/94

Eric Wilson 6/24/94

E. Wilson 6/24/94

- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f
- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

Balloon Seal:
- Expand proximal balloon shaft in a .048 ID capture tube.
- Trim to 7mm
- Insert a .015 mandrel into the inflation lumen.
- Slide .039 oval split sheath onto catheter.
- Slide sheath over proximal portion of the balloon and heat seal at 350° f
- Flatten with a flat smooth block
- Remove inflation/deflation mandrel.
- Tip seal using a "Balloon Buncher Tip Sealer"
- **Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"**

Proximal End:
- Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.
- Insert two-.018 Teflon coated mandrels into both lumens.
- Neck using an autonecker.
- **Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm** (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

Inner Member Assembly:
- Cut a 125cm piece of Graphite inner member material.
- Insert a .017 mandrel through the Graphite.
- Neck the Graphite to .021 OD using an autonecker.
- **Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm** (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.
- Insert the necked graphite into the flared guidewire lumen.
- Insert a .012 mandrel into the Polyimide.
- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel tubing.
- **Parameters: Temp = 350° f** (Hot Box)
- Remove the .012 mandrel from the Polyimide.

Proximal Shaft Assembly:
- Cut a 110cm piece of PEEK.
- Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)
- Trim the expanded portion 5-6mm
- Cut the PEEK 102 cm from the proximal end of the expanded portion.
- Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420
  Note: do not allow the adhesive to wick into the Polyimide tubing.
  Note: do not force the unexpanded PEEK over the Inflation lumen.

6/24/94 M Adams

E. Wilson 6/24/94

E. Wilson 6/24/94

Two-Arm Assembly:
- Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. ***Note: use a .018 Teflon mandrel in the graphite.***
- Attach the IM cup to the twoarm with a centerport.
- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350
- Attach the OM cup to the twoarm and tighten the nosecone and centerport
- UV cure on each side of the nosecone for 50 seconds.

Final Assembly:
- Trim tip to 3.0mm
- Tip Sand
- Microglide and Sheath

Conclusion: The 100% HDPE and the 83/13/4 blend performed better than the 75/25 LLDPE catheters. The 83/13/4 blend tracked over the wire with ease. It was mentioned that "this is the best I have seen in a while" the guidewire movement was rated 3.75 on a scale of 1 -5 with 5 being the best. Both the 100% and the 83/13/4% blend had good push however the 100% was slightly better. The 100% HDPE and the 83/13/4% blend seem to follow the wire and was less prone to prolapsing whereas the 75/25% seem to press up against the walls of the artery. (for more details see heart model evaluation notes)

R Cheung 6/24/94

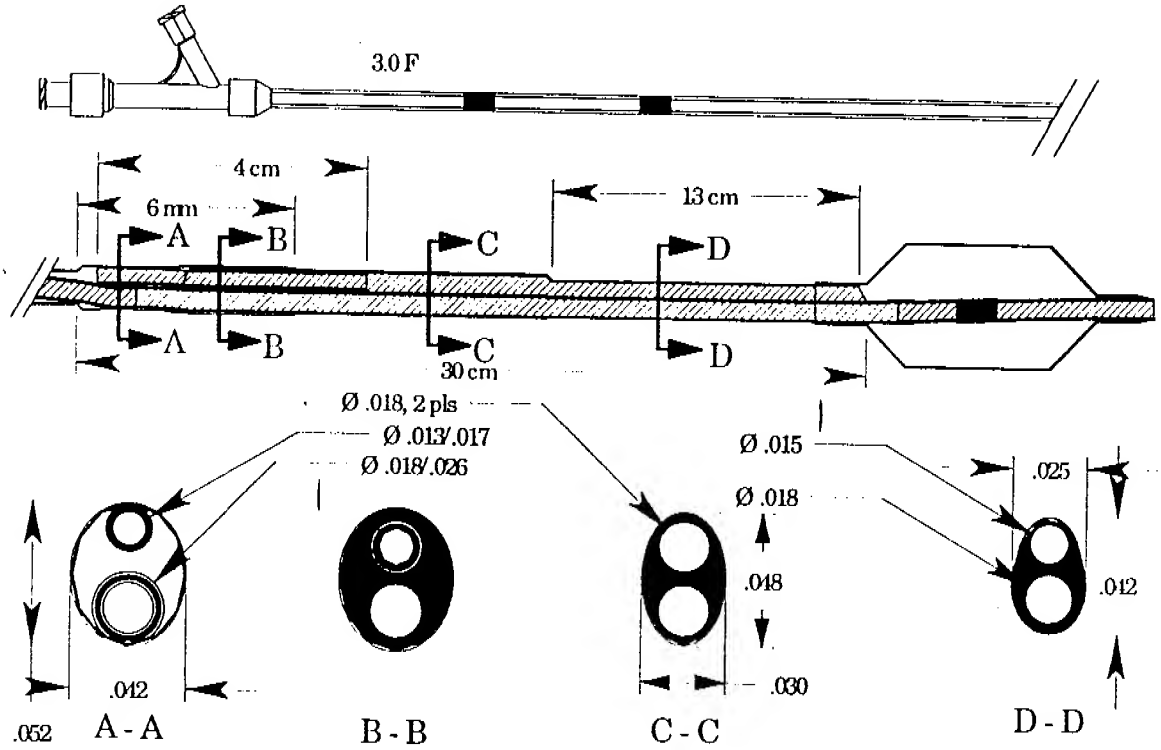
E. Wilson 6/24/94

Eric Wilson 6/24/94

CONFIDENTIAL

.014 Platform Elliptical OTW

Dan Cox
6-10-94



VR Chevrier 6/24/94

Eric Wilson 6/24/94

E. Wilson 6/24/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 6/20/94

Project Engineer: Dan Cox Wet: ✓ Dry: _____

Clinical Research Coordinator: Colleen McQueen

Control Catheter Used: None

Guiding Catheter: 7F JL3.5 PG Guide Wire: HTF TL

(1) Product design/performance goals:
PEEK proximal outer shaft, Graphite/PE inner member; Coaxial proximal, elliptical dual lumen distally. Dual lumen is HDPE (clear)

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	○	○	○
Comments:					
2. Tip length:	○	○	○	○	○
Comments:					
3. Smoothness of transition:					
A. Distal to to balloon:	○	○	○	○	○
B. Balloon to shaft:	○	○	○	○	○
C. Shaft transitions:	○	○	○	○	○
Comments: B: Pretty smooth looks good C: A little rough					
4. Flexibility of shaft:					
A. Proximal shaft:	○	○	○	○	○
B. Distal shaft:	○	○	○	○	○
Comments: B: Good					

V.F. Cherry 6/24/94 (See Reverse)

E. Wilson 6/24/94

5. Ease of prep: Prep method: _____

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

6. Inflation and deflation times:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Inflation time: _____ Deflation time: _____

Contrast & dilution: _____ Inflation device: _____

Comments: _____

7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

8. Trackability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Tracks well. Front end flexible enough to track very well

9. Pushability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Has good push. Transmits push 1:1 Follows shape of guidewire

10. Guide back out: Yes ___ No ___

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

11. Guide wire movement:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: A little heavy 3.75 in septal

12. Dimensions (list size and area):

13. Did product meet design goals? Yes ___ No ___

Overall comments:
Lesion in septal is .044". With .037" lesion in diagonal it does not square off when pushing as much as (3). About like (2).

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

E Wilson 6/24/94

R Cherry 6/24/94

E Wilson 6/24/94

E— W— 6/24/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: ~14 Platform OTW Date: 6/20/94

Project Engineer: _____ Wet: _____ Dry: _____

Clinical Research Coordinator: _____

Control Catheter Used: _____

Guiding Catheter: _____ Guide Wire: _____

(2) Product design/performance goals:
Same as (1) except dual lumen is 83% HDPE/13% LLDPE/4% graphite

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	○	○	○
Comments:					
2. Tip length:	○	○	○	○	○
Comments:					
3. Smoothness of transition:					
A. Distal tip to balloon:	○	○	○	○	○
B. Balloon to shaft:	○	○	○	○	○
C. Shaft transitions:	○	○	○	○	○
Comments: B: Same as (1)					
C: Seems a little shorter and less ledge than (1), but still a little ledge.					
4. Flexibility of shaft:					
A. Proximal shaft:	○	○	○	○	○
B. Distal shaft:	○	○	○	○	○
Comments: B: About same as (1). Maybe a little more flexible than (1)					

Mathews 6/24/94

(See Reverse)

E— W— 6/24/94

5. Ease of prep: Prep method: _____

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

6. Inflation and deflation times:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Inflation time: _____ Deflation time: _____

Contrast & dilution: _____ Inflation device: _____

Comments: _____

7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

8. Trackability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Tracked better than ① until it hit lesion

9. Pushability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Follows wire same as ① Pushes better than ① Good back end push

10. Guide back out: Yes ___ No ___

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Like a sleek effortless to cross lesion and profile seems better bigger than ①

11. Guide wire movement:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: 3.5 in septal No big differances to ①

12. Dimensions (list size and area):

13. Did product meet design goals? Yes ___ No ___

Overall comments:
With 077 lesion in diagonal this still tracked the best and did not square off in the artery like ③. This is the best catheter overall.

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

E. Willis 6/24/94

VK Chevy 6/24/94

E. Willis 6/24/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 6/20/94

Project Engineer: Wet: Dry:

Clinical Research Coordinator:

Control Catheter Used:

Guiding Catheter: Guide Wire:

Product design/performance goals:
Same as ① except dual lumen is 75% HDPE/25% LLDPE (white) ③

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	○	○	○
Comments:					
2. Tip length:	○	○	○	○	○
Comments:					
3. Smoothness of transition:					
A. Distal tip to balloon:	○	○	○	○	○
B. Balloon to shaft:	○	○	○	○	○
C. Shaft transitions:	○	○	○	○	○
Comments: B: Good nice and smooth & C: Nice and smooth best of all					
4. Flexibility of shaft:					
A. Proximal shaft:	○	○	○	○	○
B. Distal shaft:	○	○	○	○	○
Comments: B: Less stiff than ① about same as ②					

En White 6/24/94

H Cheung 6/24/94

(See Reverse)

En White 6/24/94

5. Ease of prep: Prep method: _____

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

6. Inflation and deflation times:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Inflation time: _____ Deflation time: _____

Contrast & dilution: 50/50 Inflation device: _____

Comments: _____

7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

8. Trackability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: About same as (1) Not as good as (2)

9. Pushability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Push is pretty good. Doesn't square off in vessel like 1 when you push.

10. Guide back out: Yes ___ No ___

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

11. Guide wire movement:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Pretty good. 3.75 in septal.

12. Dimensions (list size and area):

13. Did product meet design goals? Yes ___ No ___

Overall comments: Tracked well to .037 lesion in diagonal, but catheter squared off in artery when pushing against lesion

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

6/24/94

6/24/94

6/24/94

PROPERTY OF ADVANCED CARDIOVASCULAR SYSTEMS, INC.

Advanced Cardiovascular Systems, Inc.
3200 Lakeside Drive
P.O. Box 58167
Santa Clara, CA 95052-8167

NAME ERIC WILLIAMS
DEPT. 1471
LAB. NOTEBOOK NO. 1220
ISSUE DATE 08/20/93
RETURN DATE 8/11/94

RETURN TO DOCUMENT CONTROL FOR ARCHIVING.

54

Date: 5/25/94

Title: Shaft Material Evaluation

Objective: To evaluate various potential shaft materials

Materials: EVAL Extrusion # 12-143A, EVAL Extrusion # 12-142A, AERN Nylon Ext # 11-221-1, Grivory Nylon Ext # 10-547-6, Grivory Nylon Ext # 10-548-1, PPS Ext # 10-556-1, Isoplast Ext # 10-531-1, PEEK 381G and PES Ext# 10-576-1

Procedure: Rupture test 10 samples of the EVAL material and 5 samples each of the other materials. Parameters: Water Temp=37degC, Start Pressure=60psi, Increments=15psi, Hold time=15sec

Results:

Material	Ext #	ID/OD	Average Rupt	Std Dev
EVAL	12-143A	.017/.021	217.5	14.57738
EVAL	12-142A	.032/.038	123	6.3245553
AERN NYLON	11-221-1	.031/.038	291	8.2158384
GRIVORY NYLON	10-547-6	.032/.039	414	8.2158384
GRIVORY NYLON	10-548-1	.018/.025	500	8.2158384
ISOPLAT	10-531-1	.031/.038	387	16.431677
PPS	10-556-1	.031/.038	411	8.2158384
PES	10-576-1	.032/.039	500	0
PEEK	NA	.032/.038	500	0

Material	Sample #	Rupture	Material	Sample #	Rupture	Material	Sample #	Rupture
EVAL (Inner Mem)	1	210	EVAL	1	120	AERN	1	300
	2	255		2	120		2	285
	3	210		3	120		3	300
	4	210		4	120		4	285
	5	210		5	135		5	285
	6	210		6	120		6	
	7	210		7	120		7	
	8	210		8	135		8	
	9	225		9	120		9	
	10	225		10	120		10	

Material	Sample #	Rupture	Material	Sample #	Rupture	Material	Sample #	Rupture
GRIVORY 547	1	405	GRIVORY 548	1	500	PEEK	1	500
	2	420		2	500		2	500
	3	405		3	500		3	500
	4	420		4	500		4	500
	5	420		5	500		5	500

Material	Sample #	Rupture	Material	Sample #	Rupture	Material	Sample #	Rupture
ISOPLAT	1	375	PPS	1	405	PES	1	500
	2	375		2	405		2	500
	3	405		3	420		3	500
	4	405		4	420		4	500
	5	375		5	405		5	500

5/25/94 McClung

5/25/94

ate; 5/27/94

Date: 5/27/94

Title: PEEK To Elliptical Transition Development

Objective: To evaluate various concepts for improving the transition from the PEEK outer shaft to the elliptical distal dual lumen.

Materials: Graphite Extrusion V-466-1, PEEK 3816, HDPE SA200247, Alethon Extrusion 12-083, Stainless Steel .007>.003 mandrels, Polyimide "Hudson" .013 x .017, and Loctite 414

Procedure:

Concept 1
PEEK to Elliptical. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Concept 2
PEEK to Elliptical with Intermediate Shaft. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f Cut a 3cm piece of HDPE flare one end so that it fits over the elliptical tubing. Using a .045 Teflon capture tube heat bond the HDPE to the elliptical tubing. Flare one end of the PEEK to an ID that will allow it to fit over the HDPE.Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Concept 3
PEEK to Elliptical with .007>.003 tapered mandrel in the inflation lumen. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F trim to 5mm remove mandrel from one of the lumens and insert a 4 cm of tapered mandrel inside that lumen wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

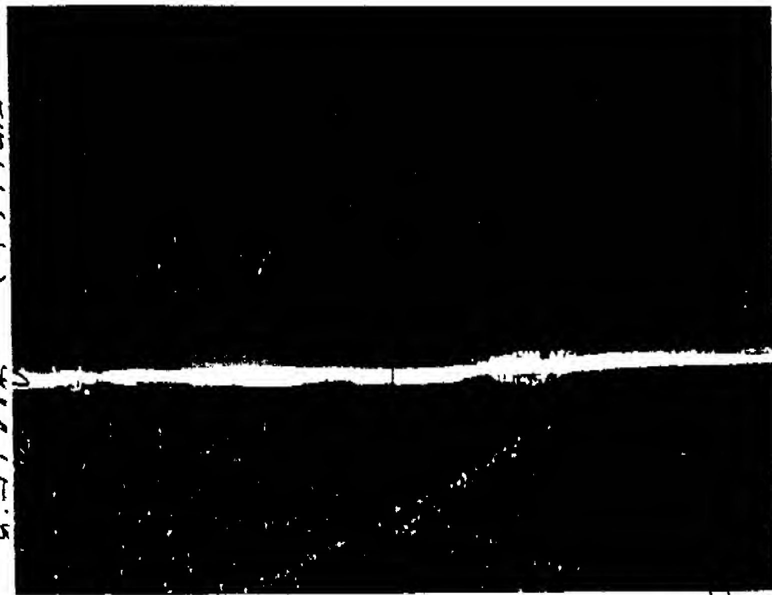
Conclusion: Concept 1 was easily assembled and had a fairly good transition from PEEK to elliptical due primarily to the Polyimide in the inflation lumen; the joint was smooth and had an OD of .040x.046. Concept 2 required additional steps to build and yet it was inconclusive about which had a better transition. The OD measured .040x.047. Concept 3 had an improved transition over the first two however it was far more difficult to assemble and the wire was too large and could possibly impede deflation.

E. Williams 5/27/94

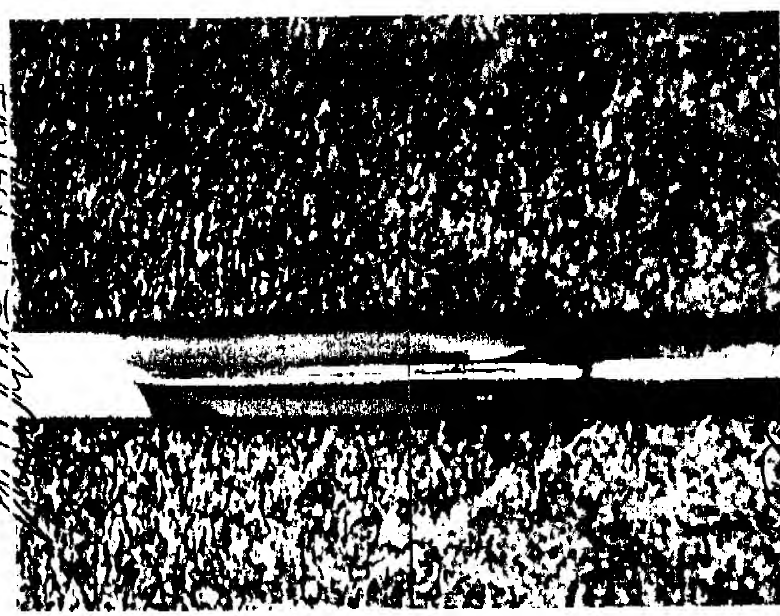
6/15/94

OVER →

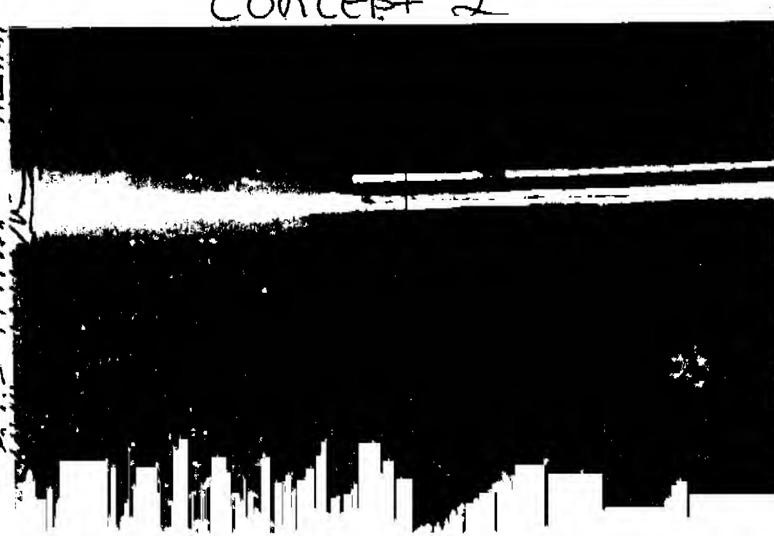
E. Williams 5/27/94



Concept 1



Concept 2



Date: 5/27/94

Title: PEEK to Elliptical Intermediate vs No Intermediate Shaft

Objective: To compare and evaluate the performance of a PEEK to elliptical OTW catheter with and without a intermediate shaft.

Procedure:

Tooling: .011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.
.025, .031, .039. 043 and .048 Teflon capture tubing.
Razor blades, Hot box, and Induction heater

Materials:

Description	Part Number	Comments
Elliptical dual lumen	~~Ext. # 12-110A~~ E.W 6/2-4/94	75/25 Alathon/LDPE
Intermediate shaft	Ext. # 12-083	Alathon 6210
IM	Ext. # V-466-1	Graphite
Süff Shaft	Vendor# 02-149	PEEK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	----------
Distal tip Material	Ext. # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	----------
Gold Bands	RM500340	----------
Loctite	RM60563	414
Loctite	RM60124	420
Loctite	RM60562	350

Assembly Instructions: (Distal Elliptical)

- Cut approximately 40 cm of the elliptical shaped tubing.
- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen .
- Neck the material down to .026 x .045 +/- .001.
- **Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm** Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

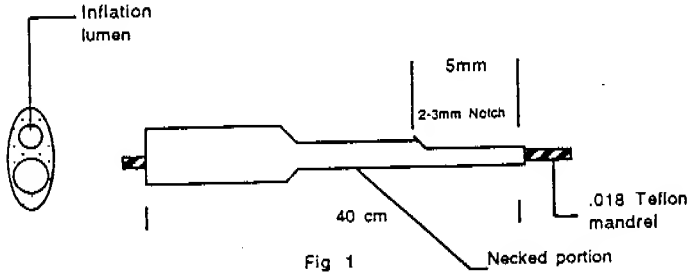


Fig 1

5/27/94

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Distal Tip:
- Cut the graphite to approximately 20 cm.
- Neck the graphite to .021 OD using an autonecker.
- **Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm**
- Slide the gold band over the necked portion.
- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f
- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

Balloon Seal:
- Expand proximal balloon shaft in a .048 ID capture tube.
- Trim to 7mm
- Insert a .015 mandrel into the inflation lumen.
- Slide .039 oval split sheath onto catheter.
- Slide sheath over proximal portion of the balloon and heat seal at 350° f
- Remove inflation/deflation mandrel.
- Tip seal using a "Balloon Buncher Tip Sealer"
- **Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"**

Proximal End:
- Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.
- Insert two-.018 Teflon coated mandrels into both lumens.
- Neck using an autonecker.
- **Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm** (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of polyimide into the inflation lumen. Tack the polyimide into place with a drop of Loctite 420.

Inner Member Assembly:
- Cut a 160cm piece of Graphite inner member material.
- Insert a .017 mandrel through the Graphite.
- Neck the Graphite to .021 OD using an autonecker.
- **Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm** (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.
- Insert the necked graphite into the flared guidewire lumen.
- Insert a .012 mandrel into the polyimide.
- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel tubing.
- **Parameters: Temp = 350° f** (Hot Box)
- Remove the .012 mandrel from the polyimide.

Proximal Shaft Assembly:
- Cut a 110cm piece of PEEK.
- Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)
- Trim the expanded portion 5-6mm
- Cut the PEEK 102 cm from the proximal end of the expanded portion.
- Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420

Note: do not allow the adhesive to wick into the polyimide tubing.
Note: do not force the unexpanded PEEK over the Inflation lumen.

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Two-Arm Assembly:
- Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. ***Note: use a .018 Teflon mandrel in the graphite.***
- Attach the IM cup to the twoarm with a centerport.
- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350
- Attach the OM cup to the twoarm and tighten the nosecone and centerport
- UV cure on each side of the nosecone for 50 seconds.

Final Assembly:
- Trim tip to 3.0mm
- Tip Sand
- Microglide and Sheath

Ref: Drawing ON pg for dimensions, E.W 6-15-94

Conclusion: Note: the Catheters built with an intermediate shaft were built by Kim Nugyen ref Lab notebook # 1152 . The Catheters were compared in a heart model and it was determined that there was little difference in the two catheters performance, however neither catheter performed very well in comparison to our coaxial design. The proximal balloon seals were perceived as stiff and having an abrupt transition.

Recommendation: Rebuild using the "no intermediate shaft" and improve the proximal balloon seal stiffness and transition. Evaluate in a heart model. Ref: heart model Results Next pase E.W 6-15-94

Eric Wilson 5/27/94

6/15/94

Eric Wilson 5/24/94

6/21/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 5/20/94

Project Engineer: Dan Cox Wet: ✓ Dry: ____

Clinical Research Coordinator: Ron Segna

Control Catheter Used: ____

Guiding Catheter: 7F JL4 PG Guide Wire: ____

(1) Product design/performance goals:
Coaxial OTW, PEEK proximal outer shaft graphite PE inner member Alathon 6210 distal shaft 2.7F PEG00 3.0 mm Balloon

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	○	○	○
Comments: Nice taper, smooth					
2. Tip length:	○	○	○	○	○
Comments:					
3. Smoothness of transition:					
A. Distal tip to balloon: Nice folding	○	○	○	○	○
B. Balloon to shaft: Can feel transition	○	○	○	○	○
C. Shaft transitions: Can feel PEEK/PE junction	○	○	○	○	○
Comments: Transitions noticeable but not a problem					
4. Flexibility of shaft:					
A. Proximal shaft:	○	○	○	○	○
B. Distal shaft:	○	○	○	○	○
Comments: Very nice					

6/24/94

R&D/2/HATTESTS.QMS (See Reverse)

Eric Wilkins 6/24/94 11/16/92

Eric Wilkins 6/21/94

6/24/94

5. Ease of prep: Prep method: _____

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Fine

6. Inflation and deflation times:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Inflation time: _____ Deflation time: 9 sec

Contrast & dilution: _____ Inflation device: _____

Comments: No bowing

7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

8. Trackability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Tip came around bend nicely. Took contour of wire nicely

9. Pushability:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Very nice. After 8 atm 60 sec no support got 70% into lesion and with support got all the way into lesion

10. Guide back out: Yes ___ No ___

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Fully sheathed itself (.043) with light guide support

11. Guide wire movement:

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Initially smooth. Slightly heavier in septal

12. Dimensions (list size and area):

13. Did product meet design goals? Yes ___ No ___

Overall comments: followed contour of wire even with hard pushing. Got it to kink and prolapse like (2) except a lot more difficult to prolapse

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

6/21/94

6/21/94

6/21/94

6/21/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 5/20/94

Project Engineer: Cox Wet: Dry:

Clinical Research Coordinator: See Foo

Control Catheter Used:

Guiding Catheter: Guide Wire:

(2) Product design/performance goals:
Coaxial proximal PEEK outer shaft, graphite PE inner member
75% HDPE/25% LLDPE elliptical distal shaft 3.0 mm PE600

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	X	○	○
Comments:					
2. Tip length:	○	○	X	○	○
Comments:					
3. Smoothness of transition:					
A. Distal tip to balloon: Not as nice as ① in fold	○	○	○	X	○
B. Balloon to shaft: Smoother than ① but bulky compared to shaft	○	○	○	X	○
C. Shaft transitions: Nice, smooth	○	X in abruptness, not a lot	○	○	○
Comments: B					
4. Flexibility of shaft:					
A. Proximal shaft:	○	○	○	○	○
B. Distal shaft:	○	○	○	○	○
Comments: B: A little more flexible, not necessarily better					

V Chen 6/24/94

Eric Wilson 6/21/94

Eric Wilson 6/21/94

6/21/94

A

5. **Ease of prep:** Prep method: _____

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Fine

6. **Inflation and deflation times:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Inflation time: _____ Deflation time: 8 sec

Contrast & dilution: _____ Inflation device: _____

Comments: Bowing at 8 atm like (3)

7. **General appearance of dilatation catheter during inflation and deflation (note bowing and folding):**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: _____

8. **Trackability:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse X | Significantly Worse ○

Comments: Proximal seal was stiff, did not go around bend into septal Does not hug wire like (1).

9. **Pushability:**

Significantly Better ○ | Somewhat Better ○ | Same As X | Somewhat Worse ○ | Significantly Worse ○

Comments: Good fully tracked w guide support. After 8 atm, got front of balloon into 045 lesion. Got all the way in with guide support.

10. **Guide back out:** Yes ___ No ___

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Lightly seated just got tip into lesion (043)

11. **Guide wire movement:**

Significantly Better ○ | Somewhat Better ○ | Same As ○ | Somewhat Worse ○ | Significantly Worse ○

Comments: Slightly worse than (1)

12. **Dimensions (list size and area):**

13. **Did product meet design goals?** Yes ___ No ___

Overall comments:
Kept pushing until distal shaft prolapse. It went into circ and LAD and kinked when balloon was stuck in lesion in septal

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

6/24/94

R&D/2/HATTEST3.CMS

2/

6/21/94

11/16/92

6/21/94

Advanced Cardiovascular Systems, Inc.

ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product: 014 Platform OTW Date: 5/20/94

Project Engineer: Cox Wet: Dry:

Clinical Research Coordinator: Sejna

Control Catheter Used:

Guiding Catheter: Guide Wire:

(3) Product design/performance goals:
Same as (2) except has 10 cm intermediate Alathon stiffshaft between elliptical distal and PEEK, 3.0 mm PE600

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
1. Tip softness:	○	○	○	○	○

Comments: Nice taper

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
2. Tip length:	○	○	○	○	○

Comments: A little shorter

3. Smoothness of transition:

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
A. Distal tip to balloon:	○	○	X	○	○
B. Balloon to shaft: Like (2)	○	○	○	X	○
C. Shaft transitions:	○	○	○	○	○

Comments: C: Both transitions are nice and smooth. More subtle switch from PEEK to elliptical. PEEK to PE feels like (1), PE to elliptical is nice

4. Flexibility of shaft:

	Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
A. Proximal shaft:	○	○	○	○	○
B. Distal shaft: Same as (2)	○	○	○	○	○

Comments:

6/24/94

6/24/94

6/24/94

2119.1

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5. Ease of prep: Prep method: _____

Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
○	○	○	○	○

Comments: _____

6. Inflation and deflation times:

Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
○	○	○	○	○

Inflation time: _____ Deflation time: 12 sec hard to see

Contrast & dilution: _____ Inflation device: _____

Comments: Same

7. General appearance of dilatation catheter during inflation and deflation (note bowing and folding):

Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
○	○	○	○	○

Comments: Some bowing Inner member rides side of balloon at 8 atm.

8. Trackability:

Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
○	○	○	○	○

Comments: _____

9. Pushability:

Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
○	○	○	○	○

Comments: Got 55% into lesion after 8 atm inflation. Good push. Distal shaft would have prolapsed into circ with more pushing.

10. Guide back out: Yes ___ No ___

Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
○	○	○	○	○

Comments: Lightly seated got just shoulders into sheath

11. Guide wire movement:

Significantly Better	Somewhat Better	Same As	Somewhat Worse	Significantly Worse
○	○	○	X	○

Comments: Not as good as ① or ② even before catheter in anatomy and after use.

12. Dimensions (list size and area):

13. Did product meet design goals? Yes ___ No ___

Overall comments:
No noticeable effect due to change in transition from ②. Did not follow contour of wire with heavy pushing. Looked easier to prolapse than ①

Recommend For Animal Studies?

Yes ___ No ___ N/A ___

R&D/2/HRTTESTS.QMS

Eric Wilson 6/24/94

11/16/92

Eric Wilson 6/24/94

Eric Wilson 6/21/94

Eric Walker 6/24/94

Date: 6/21/94

Title: Coax w/PEEK - Elliptical

Objective: To evaluate these catheters (with improved proximal balloon seal and guidewire movement) versus the catheters in the previous heart model. Ref pg. 57

Procedure: **Note:** Ref drawing for dimensions

Tooling: .011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels. .025, .031, .039. 043 and .048 Teflon capture tubing. Razor blades, Hot box, and Induction heater

Materials:

Description	Part Number	Comments
Elliptical dual lumen	N/A R&D	75/25 Alathon/LDPE
Intermediate shaft	Ext. # 12-083	Alathon 6210
IM	Ext. # V-466-1	Graphite
Stiff Shaft	Vendor# 02-149	PEEK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	----------
Distal tip Material	Ext. # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	----------
Gold Bands	RM500340	----------
Loctite	RM60563	414
Loctite	RM60124	420
Loctite	RM60562	350

Assembly Instructions: (Distal Elliptical)

- Cut approximately 40 cm of the elliptical shaped tubing.
- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to .026 x .045 +/- .001.
- **Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm** Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

Distal Tip:

- Cut the graphite to approximately 20 cm.
- Neck the graphite to .021 OD using an autonecker.
- **Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm**
- Slide the gold band over the necked portion.
- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f
- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

R Owens 6/24/94

Eric Walker 6/24/94

E. Wilk 6/24/94

Balloon Seal:
- Expand proximal balloon shaft in a .048 ID capture tube.
- Trim to 7mm
- Insert a .015 mandrel into the inflation lumen.
- Slide .039 oval split sheath onto catheter.
- Slide sheath over proximal portion of the balloon and heat seal at 350° f
- Flatten with a flat smooth block
- Remove inflation/deflation mandrel.
- Tip seal using a "Balloon Buncher Tip Sealer"
- **Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"**

Proximal End:
- Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.
- Insert two-.018 Teflon coated mandrels into both lumens.
- Neck using an autonecker.
- **Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm** (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

Inner Member Assembly:
- Cut a 125cm piece of Graphite inner member material.
- Insert a .017 mandrel through the Graphite.
- Neck the Graphite to .021 OD using an autonecker.
- **Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm** (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.
- Insert the necked graphite into the flared guidewire lumen.
- Insert a .012 mandrel into the Polyimide.
- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel tubing.
- **Parameters: Temp = 350° f** (Hot Box)
- Remove the .012 mandrel from the Polyimide.

Proximal Shaft Assembly:
- Cut a 110cm piece of PEEK.
- Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)
- Trim the expanded portion 5-6mm
- Cut the PEEK 102 cm from the proximal end of the expanded portion.
- Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420

Note: do not allow the adhesive to wick into the Polyimide tubing.
Note: do not force the unexpanded PEEK over the Inflation lumen.

E. Wilk 6/24/94

V.C. Clerx 6/24/94

Eric Wild 6/24/94

Two-Arm Assembly:
- Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. ***Note: use a .018 Teflon mandrel in the graphite.***
- Attach the IM cup to the twoarm with a centerport.
- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350
- Attach the OM cup to the twoarm and tighten the nosecone and centerport
- UV cure on each side of the nosecone for 50 seconds.

Final Assembly:
- Trim tip to 3.0mm
- Tip Sand
- Microglide and Sheath

Conclusion: These catheters performed better then the catheters in the previous heart model. The proximal seals were improved by maintaining a flat geometry. This was accomplished by using a smooth flat block to flatten the bond area while it's in the capture tube. Although these catheters were better then the previous elliptical units they were not as good as the coaxial and could use some improvements. The guidewire movement was better than before but again not as good as the coaxial. The catheters did not track as well and seem to prolapse in the Aorta when the guide was backed out and force was applied to the catheter.

Recommendation: It was recommended that we evaluate different materials transitions and dimensions to reduce the prolapsing. Refine the inner member junction to improve wire movement. Another heart model was tentatively scheduled. (see heart model evaluation notes)

6/24/94

Eric Wild 6/24/94